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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/919,048	07/30/2001	Timothy J. O'Brien	D6223CIP/A/D/CIP	4713

7590 08/13/2003

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EXAMINER	
HARRIS, ALANA M	

ART UNIT	PAPER NUMBER
1642	

DATE MAILED: 08/13/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/919,048	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Alana M. Harris, Ph.D.	1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 June 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 20-31* is/are pending in the application.

4a) Of the above claim(s) *1-17 and 24-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *18 and 20-23* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Group VII (claims 18-23, SEQ ID NO: 148) in Paper No. 10, received June 3, 2003 is acknowledged.

2. Claims 1-31 are pending.

Claims 1-17 and 24-31, drawn to non-elected inventions are withdrawn from examination.

Claim 19 has been cancelled.

Claims 18 and 20-23 are examined on the merits.

Drawings

3. The drawings are objected to because of reasons cited on attached form PTO 948 completed by draftsman. Correction is required.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

5. Claims 18 and 20-23 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to

which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Applicants broadly claim a method of producing immune-activated T cells directed toward hepsin, as well as the administration of said cells. Claims 18 and 20 read on the method of making the immune-activated T cells comprising exposing said cells to a hepsin fragment that is 9-residues to 20-residues long. The fragment has not been defined structurally. Claim 18 characterizes the fragment or protein as lacking hepsin protease activity. The specification does not sufficiently provide guidance in the selection of particular fragments, which must lack protease activity. There is no disclosure supporting that arbitrary fragments of any length are capable of acting in the manner in which the method requires, for instance to activate immune cells. Likewise, the dendritic cells that are activated by the broad method make encompass artifacts in which may not be the subset of T cells capable of eliciting a proper immune response. It follows that the population of individuals designated to receive the administration of these activated cells is ill-defined. There is no correlation between SEQ ID NO: 148 and cancer, nor has it been established in the art that the production of immune cells by mere exposure to a protein fragment would render an anti-cancer agent effective for use in the treatment of any disorder or as a preventive agent. Thus, undue experimentation would be required to make and use the produced activated dendritic cells of the broadly claimed invention.

There is inadequate direction or guidance provided to assist one skilled in the art in the selection of which diseases and disorders that fall under the scope of cancer,

autoimmune and alloimmune diseases that could be treated with the claimed vaccine with therapeutic effectiveness. Tumors are classified as immunogenic or non-immunogenic, solid or hematological in nature. Effective cancer strategies should be designed to deal effectively with the nature of each of these classifications. One cannot extrapolate the teachings of the specification to the plethora of disorders encompassed by the term cancer because it is well known that the art of anticancer drug discovery for cancer therapy is highly unpredictable, for example, Gura (Science 278:1041-1042, 1997) teaches that researchers face the problem of sifting through potential anticancer agents to find ones promising enough to make human clinical trials worthwhile (see first paragraph of page 1041). Further, the refractory nature of cancer to drugs is well known in the art and additionally complicated by drug medications that are composed of several agents. Jain (Sci. Am., 271:58-65, 1994) teaches that tumors resist penetration by drugs (see page 58, column 1, paragraph 2) and that "scientists need to put expanded effort into uncovering the reasons why therapeutic agents that show encouraging promise in the laboratory often turn out to be ineffective in the treatment of common solid tumors", see page 65, column 3. It is clear that based on the state of the art, in the absence of experimental evidence, no one skilled in the art would accept the assertion that the activated dendritic cells made by the broadly claimed method would function as contemplated in the specification, i.e. broad treatment of cancer. In addition, the activated immune cell formulation may not reach its target because of its inability to penetrate tissues or cells where its activity is to be exerted, may be absorbed by fluids, cells and tissues where the formulation has no effect, circulation into the target area

may be insufficient to carry the formulation and a large enough local concentration may not be established. The specification provides insufficient guidance with regard to these issues. The specification also does not present sufficient working examples, which would provide guidance and significant preponderance of predictability to one skilled in the art the use of the claimed vaccine comprising more than one cell type would be therapeutically effective with a reasonable expectation of success. Limited evidence has been provided which would allow one of skill in the art to predict the efficacy of the dendritic cells to confer protective immunity or generate an immune response in any and all cancers with a reasonable expectation of success based on the analysis set forth. In view of the above, one of skill in the art would be forced into undue experimentation to practice implementation of the claimed invention.

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 18 and 20-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

a. The recitation "said activated dendritic cells" in claim 18 lacks proper antecedent bases.

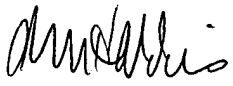
b. Claim 23 is vague and indefinite in the recitation "suspected of having a cancer or is at risk of getting a cancer". It is not what type of cancer is being referenced or how a population is assessed in order to determine which individuals

could have cancer or may have cancer. Accordingly, the metes and bounds cannot be determined.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alana M. Harris, Ph.D. whose telephone number is (703) 306-5880. The examiner can normally be reached on 7:00 am to 4:30 pm, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, Ph.D. can be reached on (703) 308-3995. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4315 for regular communications and (703) 308-4315 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703)308-0196.



Alana M. Harris, Ph.D.
August 11, 2003